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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 16

Application Number: 09/655,667
Filing Date: September 06, 2000
Appellant(s): BRIEGS ET AL.

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Laura C. Brutman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 29 March 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1, 6, 7, 11, 13, 14, and 43 stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

Appellant's brief includes a statement that claims 2-5, 15-17, 19-24, 28, 32-38, and 44 stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

Appellant's brief includes a statement that claims 25-27, 29, 30, 31, and 45 stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

Appellant's brief includes a statement that claims 8-10 and 12 stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

1. 5, 991, 731A	Colon et al.	11-1999
2. 5, 995, 937A	DeBusk et al.	11-1999
3. 5, 737, 539A	Edelson et al.	04-1998
4. 5, 734, 883A	Umen et al.	03-1998

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

NOTE: The rejections of claims 35-38 under 35 U.S.C. § 112, second paragraph are hereby withdrawn in light of Applicant's arguments given at page 15 of the Appeal Brief (Section VIII, paragraph (O)).

Claims 1-17, 19-38, and 43-45 are rejected under 35 U.S.C. § 103(a).

These rejections are set forth in prior Office Action, Paper No. 13 and reproduced hereinbelow. The rejections that appear below substantially repeat the rejections made in the previous Office Action (Paper No.13). The text of those sections of Title 35 U.S. Code relied upon in the Examiner's Answer is set forth in the previous Office actions, Paper No. 13.

1. Claims 1, 6-7, 11, 13, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al., U.S. Patent Number 5, 991, 731 in view of DeBusk et al., U.S. Patent Number 5, 995, 937.

(A) As per claim 1, Colon teaches a clinical trial management system comprising:

a main database of information concerning prior clinical trials and resources available to conduct future clinical trials (Colon; see at least Abstract, Figure 1, Item 12, column 1, line 35 to column 2, line 4, column 2, line 58 to column 3, line 22, column 3, lines 15-23, column 6, lines 50-51, column 7, lines 45-54) , the information concerning prior clinical trials being at least in part in the form of a protocol of (a) scheduled visits of a test subject to a treatment site, (b) measurement of prescribed physical attributes of the subject during the visits and (c) administration of at least one prescribed medical product to the subject during the visit to

determine over time the subject's response thereto (Colon; Figure 4, column 1, lines 47-53, column 6, lines 1-14, column 6, line 58 to column 7, line 31);

a main processor controlling access to said main database (Colon; Figure 1, Item 13, column 3, lines 24-43); and

at least one user or investigator processor in communication with said main processor to negotiate access to said main database (Colon; Figure 1, Items 12, 18 and 21, column 1, lines 35-46).

Colon fails to explicitly disclose the protocol of a prior clinical trial being stored in said main database in the form of a software template; and

said user processor and main processor running a program that designs and tracks at said user processor of a clinical trial through access by said user processor to at least one software template in said main database and modification of the template for formulating a new clinical trial or event.

DeBusk teaches the protocol or standardization of a prior clinical trial or event being stored in said main database in the form of a software template or configurable object (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-53, column 12, line 21 to column 13, line 34, column 14, line3 to column 15, line 30); and

said user processor and main processor running a program that designs and tracks at said user processor of a clinical trial through access by said user processor to at least one software template in said main database and modification of the template or predesigned software object for formulating or creating a new clinical trial or event (DeBusk; column 6, lines 33-49, column

7, lines 40-59, column 8, lines 5-53, column 12, line 21 to column 13, line 34, column 14, line3 to column 15, line 30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the clinical trial management system, of Colon to include the protocol of a prior clinical trial being stored in said main database in the form of a software template; and said user processor and main processor running a program that designs and tracks at said user processor of a clinical trial through access by said user processor to at least one software template in said main database and modification of the template for formulating a new clinical trial or event, as taught by DeBusk, with the motivation of providing an integrated information system for us in healthcare institutions for managing, optimizing and analyzing the use of resources within that institution utilizing a modular, component-ware software structure (DeBusk; column 7, lines 11-33).

(B) As per claims 6-7, Colon and DeBusk teach a clinical trial management system as analyzed and disclosed in claim 1 above

wherein said main processor and main database are in an organizational environment which includes other databases with specialized information useful in formulating clinical trials (Colon; column 2, line 58 to column 3, lines 22, column 5, lines 14-34, column 6, lines 21-43, column 6, lines 60-66, column 7, lines 26-61); and

further including a communications link with said other databases and means for replicating or updating selected portions of the data in the other databases into the main database

(Colon; column 2, line 58 to column 3, lines 22, column 5, lines 14-34, column 6, lines 21-43, column 6, lines 60-66, column 7, lines 26-61); and

wherein the other databases are one of a human resources database of personnel and location information, a finance database of budget authorization and cost information and a clinical supplies database of information on the availability of various clinical medical products (DeBusk; column 14, line 46 to column 15, line 13).

(C) As per claims 11, 13, Colon and DeBusk teach a clinical trial management system as analyzed and disclosed in claim 1 above

wherein the program is in the form of modules (DeBusk; see at least Abstract, Figure 1, Figure 2, column 7, lines 40-58); and

wherein the program includes a reports module that generates messages to personnel concerning actions to take to advance the trial (Colon; column 2, lines 5-8, column 6, lines 39-50).

(D) As per claim 43, Colon and DeBusk teach a clinical trial management system comprising:

a main database of information concerning resources available to conduct clinical trials (Colon; see at least Abstract, Figure 1, Item 12, column 1, line 35 to column 2, line 4, column 2, line 58 to column 3, line 22, column 3, lines 15-23, column 6, lines 50-51, column 7, lines 45-54);

a main processor controlling access to said main database (Colon; Figure 1, Item 13, column 3, lines 24-43);

at least one user or investigator processor in direct communication with said main processor to negotiate access to said main database (Colon; Figure 1, Items 12, 18 and 21, column 1, lines 35-46), said user processor and main processor running a program that designs a clinical trial and the input of information with regard to the completion of tasks forming a protocol for the clinical trial and tracks the completion of the tasks at said user processor, a portion of said program printing forms determined by the data in the system (Colon; column 1, line 35 to column 2, line 4, column 6, lines 21-30, column 6, line 39 to column 7, line 54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56).

The motivations for combining the respective teachings of Colon and DeBusk are as given in the rejection of claim 1 above, and incorporated herein.

2. Claims 2-5, 15-17, 19, 20-22, 23-24, 28, 32-38, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al., U.S. Patent Number 5, 991, 731 and DeBusk et al., U.S. Patent Number 5, 995, 937 as applied to claims 1, 19, and 43 and further in view of Edelson et al, U.S. Patent Number 5, 737, 539.

(A) Claim 19 differs from claim 1 in that is a clinical trial management system comprising a subsidiary database and a subsidiary processor being in communication with a main processor to controlling replication of a portion of the data in the main database to said

subsidiary database rather than a clinical trial management system that stores the protocols of clinical trials in the form of a software template.

As per claims 2, 19, Colon and DeBusk teach a clinical trial management system as analyzed and discussed above, comprising:

a main database of information concerning resources available to conduct clinical trials (Colon; see at least Abstract, Figure 1, Item 12, column 1, line 35 to column 2, line 4, column 2, line 58 to column 3, line 22, column 3, lines 15-23, column 6, lines 50-51, column 7, lines 45-54);

a main processor controlling access to said main database (Colon; Figure 1, Item 13, column 3, lines 24-43);

at least one user or investigator processor in direct communication with said main processor to negotiate access to said main database (Colon; Figure 1, Items 12, 18 and 21, column 1, lines 35-46), said user processor and main processor running a program that designs a clinical trial or event in the form of a protocol of tasks to be completed and tracks the completion of the tasks in the protocol at said user processor (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56);

a subsidiary database (Colon; column 7, lines 45-54), (DeBusk; column 14, lines 53-56, column 15, lines 5-13);

a subsidiary processor controlling access to said subsidiary database (Colon; column 7, lines 45-54), (DeBusk; column 14, lines 53-56, column 15, lines 1-13);

at least one subsidiary user processor in communication with said subsidiary processor, said subsidiary processor and subsidiary user processor running the program so as to design and track at said subsidiary user processor a clinical trial or protocol based on data in said subsidiary database (Colon; column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56).

Colon and DeBusk fail to explicitly disclose

said subsidiary processor being in communication with said main processor to controlling replication of a portion of the data in the main database to said subsidiary database.

Edelson teaches said subsidiary processor being in communication with said main processor to controlling replication of a portion of the data in the main database to said subsidiary database (Edelson; column 48, lines 4-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the collective teachings, of Colon and DeBusk to include said subsidiary processor being in communication with said main processor to controlling replication of a portion of the data in the main database to said subsidiary database, as taught by Edelson, with the motivation of providing systems for clinical laboratory management, for medical record management for radiology management and the like, of providing novel professional data management systems that can yield comparable benefits in other professional spheres where professionals are responsible for solving client or customer problems, and of ensuring that all users in the network constantly share the same level of information (Edelson; column 7, lines 11-33, column 48, lines 4-24).

The motivations for combining the respective teachings of Colon and DeBusk are as given in the rejection of claim 1 above, and incorporated herein.

(B) As per claims 3-5, 15-16, 20-22, 32-33, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and discussed in claims 1, 2, and 19 above,

wherein said subsidiary processor, subsidiary database and subsidiary user processor are located in a certain geographical location remote from the location of said main database and said main processor (Colon; column 1, lines 35-62, column 2, line 58 to column 3, line 12, column 3, line 50 to column 4, line 22, column 5, lines 14-24, column 6, lines 21-32, column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56);

wherein the portion of data replicated to said subsidiary database relates to clinical trials in said certain geographical location (Edelson; column 7, lines 15-32, column 8, lines 4-10, column 47, lines 8-20, column 48, lines 4-46);

wherein the portion of data in said subsidiary database includes at least one template of a clinical trial protocol previously created according to requirements prevalent in the certain geographical location (DeBusk; column 8, lines 5-20, column 10, line 29 to column 11, line 53, column 12, lines 21-31); and

wherein the portion of data in said subsidiary database can be altered by said subsidiary user processor and the data in the main database can be altered by said user processor (Colon; column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56),

(Edelson; column 7, lines 15-32, column 8, lines 4-10, column 47, lines 8-20, column 48, lines 4-46);

wherein said main processor and said subsidiary processor periodically operate to synchronize the replicated and changed data at said main database and said subsidiary database, with changes at said main database predominating over changes at said subsidiary database (Edelson; column 7, lines 15-32, column 8, lines 4-10, column 47, lines 8-20, column 48, lines 4-46));

wherein the program running on said subsidiary processor includes a site management module for indicating the conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location (Colon; Abstract, Figure 1, Figure 4, column 1, line 47 to column 2, line 26, column 4, lines 60-65, column 5, lines 14-24), (Edelson, column 24, lines 40-59, column 38, lines 41-48, column 48, lines 47-64, column 52, lines 57-65); and

wherein information about the completion of tasks in the protocol at the certain geographical location are entered by the subsidiary user processor in the subsidiary database, and the site management module updates the portion of the protocol related thereto (Colon; Figure 3, column 1, line 35 to column 2, line 4, column 4, lines 26-36, column 6, lines 21-30, column 6, line 39 to column 7, line 54), (DeBusk; column 6, lines 33-67, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 26, line 56, column 15, lines 51-56).

(C) As per claims 17, 34, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and discussed in claims 1 and 19 above, further including a portable processor running the program, said portable processor operating with said main processor to transfer or compile to the portable processor a copy of a portion of the main database related to a site for the clinical trial in a certain geographical area, said main processor locking the portion of the main database that was copied, said portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and said portable processor operating with said main processor to transfer to or upload and update the main database with the modified copy of the data and to unlock that portion of the main database (Edelson; column 7, line 43 to column 8, line 61, column 11, lines 21-27, column 43, line 48 to column 45, line 38, column 45, line 55 to column 46, line 61, column 47, lines 1-7, column 48, lines 4-31, 42-64).

(D) As per claims 23-24, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and discussed in claim 19 above, wherein said main processor and main database are in an organizational environment which includes other databases with specialized information useful in formulating clinical trials (Colon; column 2, line 58 to column 3, lines 22, column 5, lines 14-34, column 6, lines 21-43, column 6, lines 60-66, column 7, lines 26-61); and

further including a communications link with said other databases and means for replicating or updating selected portions of the data in the other databases into the main database

(Colon; column 2, line 58 to column 3, lines 22, column 5, lines 14-34, column 6, lines 21-43, column 6, lines 60-66, column 7, lines 26-61); and

wherein the other databases are one of a human resources database of personnel and location information, a finance database of budget authorization and cost information and a clinical supplies database of information on the availability of various clinical medical products (DeBusk; column 14, line 46 to column 15, line 13).

(E) As per claim 28, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and disclosed in claim 19 above

wherein the program is in the form of modules (DeBusk; see at least Abstract, Figure 1, Figure 2, column 7, lines 40-58).

(F) As per claims 35-38, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and disclosed in claim 19 above.

wherein there are a plurality of user processors located at different clinical trial sites in the geographical area in which the main processor and main database are located (Colon; column 1, lines 35-62, column 2, line 58 to column 3, line 12, column 3, line 50 to column 4, line 22, column 5, lines 14-24, column 6, lines 21-32, column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56);

wherein there are a plurality of subsidiary processors and subsidiary databases each located in respective geographical areas that are different from the geographical area in which

the main processor and main database are located (Colon; column 1, lines 35-62, column 2, line 58 to column 3, line 12, column 3, line 50 to column 4, line 22, column 5, lines 14-24, column 6, lines 21-32, column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56);

wherein there are a plurality of subsidiary user processors located in each geographical area in which a subsidiary processor and subsidiary database are located, said plurality of subsidiary user processors being connected to the subsidiary processor in their respective geographical area (Colon; column 1, lines 35-62, column 2, line 58 to column 3, line 12, column 3, line 50 to column 4, line 22, column 5, lines 14-24, column 6, lines 21-32, column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56); and

in which the geographical areas are countries (Colon; column 2, line 58 to column 3, line 10), (Edelson; column 47, lines 1-7, column 48, lines 60-64).

(G) As per claim 44, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and disclosed in claim 43 above

further including a subsidiary processor, subsidiary database and subsidiary user processor located in a certain geographical location remote from the location of said main database and said main processor (Colon; column 1, lines 35-62, column 2, line 58 to column 3, line 12, column 3, line 50 to column 4, line 22, column 5, lines 14-24, column 6, lines 21-32,

column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56); and

wherein a portion of data in the main database is replicated to said subsidiary database and relates to clinical trials in said certain geographical location (Edelson; column 7, lines 15-32, column 8, lines 4-10, column 47, lines 8-20, column 48, lines 4-46).

3. Claims 25-27, 29-30, 42, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al., U.S. Patent Number 5, 991, 731, DeBusk et al., U.S. Patent Number 5, 995, 937 and Edelson et al, U.S. Patent Number 5, 737, 539, as applied to claim 19 above, and further in view of Umen et al, U.S. Patent Number 5, 734, 883.

(A) As per claim 25, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and disclosed in claim 19 above.

Colon, DeBusk and Edelson fail to explicitly disclose a system further including a display at the user processor and subsidiary user processor which are operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task.

Umen teaches a system further including a display at the user processor and subsidiary user processor which are operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task (Umen; see at least Figure 3, Items 56c, 66, Figure 6, Figure 7, column 10, lines 22-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the collective teachings, of Colon, DeBusk and Edelson to include further including a display at the user processor and subsidiary user processor which are operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task, as taught by Umen, with the motivation of providing an automated system for organizing text and details associated with drug studies into a convenient database, and for integrating such information in the form of standard documents, providing a system that would also be desirable to be adapted for use in preparing documentation, such as Product License Applications or Establishment Licenses, in connection with studies relating to medical devices or to biological agents, such as viruses, sera, toxins, antitoxins, and the like, and providing a system that would be adapted to arranging such information in the form of documents that are compliant with each of the various manners which may be prescribed for such documents by U.S. or foreign regulatory agencies (Umen; column 2, lines 46-61).

(B) As per claims 26-27, 29-30, Colon, DeBusk, Edelson and Umen teach a clinical trial management system as analyzed and disclosed in claim 25 above

wherein said users processor and subsidiary user processors can used to input information concerning completion of tasks in the protocol, and the display is updated to show progress of the trial (Umen; see at least Figure 3, Items 58, 60, 98c, column 3, lines 51-56, column 4, lines 13-20);

wherein the program automatically indicates the completion of a major task when all of its minor related tasks are completed (Umen; column 7, lines 23-55, column 8, line 66 to column 9, line 42, column 17, line 16 to column 18, line 50);

wherein the program includes a reports module that generates reports of the status of the trial for presentation on the display (Umen, Figure 3, Item 66, Figure 5, column 5, lines 29-63, column 7, line 7 to column 8, line 8); and

wherein the program includes a reports module that generates messages to personnel concerning actions to take to advance the trial (Colon; column 2, lines 5-8, column 6, lines 39-50); and

(C) As per claim 42, Colon, DeBusk, Edelson and Umen teach a clinical trial management system as analyzed and disclosed in claim 25 above

wherein there the plan is in the form of at least one lower level plan that forms part of a higher and wherein the program automatically updates the display of the upper level plan and where an update in a lower level plan automatically update (Edelman; column 14, lines 53-60, column 15, lines 35-45, column 26, lines 19-28, 55-67), (Umen; Abstract, column 1, line 40 to column 2, line 62, column 19, lines 25-55, column 7, line 55 to column 8, line 22).

(D) As per claim 45, Colon, DeBusk, Edelson and Umen teach a clinical trial management system as analyzed and disclosed in claim 19 above

wherein the system manages a plurality of clinical trials with separate protocols, at least some of the separate protocols having major tasks made up of a plurality of minor tasks that are

common to them, and wherein the program automatically indicates the completion of a common major task in the separate protocols when all of the minor related tasks are completed (Colon; column 1, lines 47-53, column 6, line 58 to column 7, line 51), (Umen; Figure 3, column 6, line 59 to column 7, line 40, column 13, line 1 to column 14, line 67, column 15, line 64 to column 16, line 65); (Edelson; column 8, lines 46-50, column 13, lines 35-49, column 28, line 43 to column 29, line 35, column 48, lines 5-24).

4. Claims 8-10, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al., U.S. Patent Number 5, 991, 731 in view of DeBusk et al., U.S. Patent Number 5, 995, 937 as applied to claim 1 above, and further in view of Umen et al, U.S. Patent Number 5, 734, 883.

(A) As per claim 8, Colon and DeBusk teach a clinical trial management system as analyzed and disclosed in claim 1 above.

Colon and DeBusk fail to explicitly disclose a system further including a display at the user processor which is operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task.

Umen teaches a system further including a display at the user processor which is operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task (Umen; see at least Figure 3, Items 56c, 66, Figure 6, Figure 7, column 10, lines 22-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the collective teachings, of Colon and DeBusk to include further including a display at the user processor which is operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task, as taught by Umen, with the motivation of providing an automated system for organizing text and details associated with drug studies into a convenient database, and for integrating such information in the form of standard documents, providing a system that would also be desirable to be adapted for use in preparing documentation, such as Product License Applications or Establishment Licenses, in connection with studies relating to medical devices or to biological agents, such as viruses, sera, toxins, antitoxins, and the like, and providing a system that would be adapted to arranging such information in the form of documents that are compliant with each of the various manners which may be prescribed for such documents by U.S. or foreign regulatory agencies (Umen; column 2, lines 46-61).

(B) As per claims 9-10, 12, Colon, DeBusk and Umen teach a clinical trial management system as analyzed and disclosed in claim 1 above

wherein said users processor can used to input information concerning completion of tasks in the protocol, and the display is updated to show progress of the trial (Umen; see at least Figure 3, Items 58, 60, 98c, column 3, lines 51-56, column 4, lines 13-20);

wherein the program automatically indicates the completion of a major task when all of its minor related tasks are completed (Umen; column 7, lines 23-55, column 8, line 66 to column 9, line 42, column 17, line 16 to column 18, line 50); and

wherein the program includes a reports module that generates reports of the status of the trial for presentation on the display (Umen, Figure 3, Item 66, Figure 5, column 5, lines 29-63, column 7, line 7 to column 8, line 8).

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al., U.S. Patent Number 5, 991, 731 in view of DeBusk et al., U.S. Patent Number 5, 995, 937 as applied to claim 1 above, and further in view of Official Notice.

(A) As per claim 14, Colon and DeBusk teach a clinical trial management system as analyzed and disclosed in claim 1 above.

Colon and DeBusk fail to explicitly disclose a system wherein at least one of the messages is to a provider of clinical supplies for the trial to inform it of the medical products needed for the trial.

The Examiner takes Official Notice that sending a message to a provider of supplies to inform it of supplies needed is well known in the art, and in addition that it would be obvious to send a message to a provider of clinical supplies for the trial to inform it of medical products needed for the trial in a system which comprises an information system incorporating software for supply, scheduling and resource utilization management in the health-care environment (DeBusk; Abstract, column 1, lines 5-10, column 3, lines 18-25, column 6, lines 33-45, column 7, lines 11-24, column 11, lines 12-30, column 12, lines 47-54) with the motivation of streamlining the supply process while insuring that the process results in the best balance between waste minimization and standardization, in addition to the ultimate requirement that all

of the supplies required during a procedure are actually available when the procedure is conducted, and of providing the customer and the suppliers with a framework within which the suppliers can respond very rapidly to an order, while minimizing inventory, which minimizes inventory carrying costs, the risk that inventory will expire before use, tied-up capital and the skilled labor necessary to maintain the inventory and pull it for each procedure (DeBusk; column 3, lines 18-25, column 5, lines 47-52, column 11, lines 12-53). In addition, the skilled artisan motivated to notify a provider of clinical supplies of required medical products within the DeBusk invention would have likewise found it obvious to send a message to deliver that information as described above. Moreover, the Examiner respectfully submits that Appellant is not the first to invent sending messages to suppliers as described above. The use of messages to suppliers as described above was well established in the prior art and the courts have held that even if a patent does not specifically disclose a particular element, said element being within the knowledge of a skilled artisan, the patent taken in combination with that knowledge, would put the artisan in possession of the claimed invention. *In re Graves*, 36 USPQ 2d 1697 (Fed. Cir. 1995).

6. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al., U.S. Patent Number 5, 991, 731, DeBusk et al., U.S. Patent Number 5, 995, 937, Edelson et al, U.S. Patent Number 5, 737, 539, and Umen et al, U.S. Patent Number 5, 734, 883 as applied to claim 25 above and further in view of Official Notice.

(A) As per claim 31, Colon, DeBusk, Edelson and Umen teach a clinical trial management system as analyzed and disclosed in claim 25 above.

Colon, DeBusk, Edelson and Umen fail to explicitly disclose a system wherein at least one of the messages is to a provider of clinical supplies for the trial to inform it of the medical products needed for the trial.

The Examiner takes Official Notice that sending a message to a provider of supplies to inform it of supplies needed is well known in the art, and in addition that it would be obvious to send a message to a provider of clinical supplies for the trial to inform it of medical products needed for the trial in a system which comprises an information system incorporating software for supply, scheduling and resource utilization management in the health-care environment (DeBusk; Abstract, column 1, lines 5-10, column 3, lines 18-25, column 6, lines 33-45, column 7, lines 11-24, column 11, lines 12-30, column 12, lines 47-54) with the motivation of streamlining the supply process while insuring that the process results in the best balance between waste minimization and standardization, in addition to the ultimate requirement that all of the supplies required during a procedure are actually available when the procedure is conducted, and of providing the customer and the suppliers with a framework within which the suppliers can respond very rapidly to an order, while minimizing inventory, which minimizes inventory carrying costs, the risk that inventory will expire before use, tied-up capital and the skilled labor necessary to maintain the inventory and pull it for each procedure (DeBusk; column 3, lines 18-25, column 5, lines 47-52, column 11, lines 12-53). In addition, the skilled artisan motivated to notify a provider of clinical supplies of required medical products within the invention of Colon, DeBusk, Edelson and Umen would have likewise found it obvious to send a

message to deliver that information as described above. Moreover, the Examiner respectfully submits that Appellant is not the first to invent sending messages to suppliers as described above. The use of messages to suppliers as described above was well established in the prior art and the courts have held that even if a patent does not specifically disclose a particular element, said element being within the knowledge of a skilled artisan, the patent taken in combination with that knowledge, would put the artisan in possession of the claimed invention. *In re Graves*, 36 USPQ 2d 1697 (Fed. Cir. 1995).

(11) Response to Argument

In the Appeal Brief filed 29 March 2004, Appellant makes the following fifteen arguments:

(A) All Claims: None of the applied references suggest the design of a clinical trial, let alone a clinical trial based on templates created from a protocol of tasks to be completed based on old clinical trials (Issues 1-4).

(B) DeBusk does not teach the standardization of a prior clinical trial being stored in a database in the form of a software template (Issue 1).

(C) Claims 6 and 7: Colon does not teach a main processor and main database in an organizational environment that includes other databases with information for formulating clinical trials (Issue 1).

(D) Claim 43 does not differ from claim 19 in the manner suggested by the Examiner (Issue I).

(E) Claims 43 and 44: neither Colon nor DeBusk suggest the input of information with regard to completion of tasks and tracking the completion at a user processor (Issue 1).

(F) Claims 2 and 19: Colon and DeBusk also do not suggest a program that permits the design of a clinical trial in the form of a protocol of tasks to be completed and does not track the completion of the tasks in the protocol at a user processor (Issue 2).

(G) Claims 5 and 22: Edelson does not suggest a main processor and a subsidiary processor periodically operating to synchronize replicated and changed data at the main database and the subsidiary database with changes at said main database predominating over changes at said subsidiary database (Issue 2).

(H) Claims 15, 16, 32, and 33: Applied references do not suggest a site management module for indicating conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location (Issue 2).

(I) Claims 16 and 33: Neither Colon nor DeBusk suggest that information about the completion of tasks in the protocol at a certain geographical location are entered by a subsidiary user processor in a subsidiary database, and a site management module updates a portion of the protocol related thereto (Issue 2).

(J) Claims 17 and 34, Edelson does not suggest transferring from a main processor to a portable processor a copy of a portion of a main database related to a site for a clinical trial in a certain geographical area, the main processor locking the portion of the main database that was copied, the portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and the

portable processor transferring and updating the main database with the modified copy of the data and unlocking that portion of the main database (Issue 2).

(K) Claim 44: Edelson does not suggest replicating to a subsidiary database a portion of data relating to clinical trials in a certain geographical location (Issue 2).

(L) Claims 25-27 and 29-31: Umen does not suggest displaying at a user processor and subsidiary user processor which are operative to display a clinical trial protocol, a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task (Issue 3).

(M) Claims 10 and 45: None of the applied references suggests the program automatically indicating the completion of a common major task in separate protocols when all of the minor related tasks are completed (Issues 3 and 4).

(N) Prior Art Rejections (Issues 1-4).

(O) Claims 35 and 36 are sufficiently definite (Issue 5).

Examiner will address Appellant's arguments in sequence as they appear in the brief.

(A) All Claims: None of the applied references suggest the design of a clinical trial, let alone a clinical trial based on templates created from a protocol of tasks to be completed based on old clinical trials (Issues 1-4).

In response to Appellant's argument, all of the limitations which Appellant disputes are missing in the applied references have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the combined teachings of Colon, DeBusk, Edelson, and Umen,

based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the 35 USC § 103 rejections given in the preceding sections of the present document and in the prior Office Action (paper number 13), and incorporated herein. In particular, Examiner notes that a main database of information concerning prior clinical trials and resources available to conduct future clinical trials the information concerning prior clinical trials being at least in part in the form of a protocol, the protocol of a prior clinical trial being stored in said main database, and the protocol of a prior clinical trial being stored in said main database in the form of a software template are taught by the cited references. In particular, please note (Colon; see at least Abstract, Figure 1, Item 12, column 1, line 35 to column 2, line 4, column 2, line 58 to column 3, line 22, column 3, lines 15-23, column 6, lines 1-14, lines 50-51, column 6, line 58 to column 7, line 31, column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-53, column 12, line 21 to column 13, line 34, column 14, line3 to column 15, line 30) as specifically applied in the rejections given above and incorporated herein. Furthermore, with respect to Appellant's argument that the applied references do not suggest the design of a clinical trial, Examiner respectfully notes that there is nothing in the claim language of claims 1, 19, or 43 that precludes use of this system for an existing clinical trial. Additionally, Colon's "invention allows larger studies to be conducted..." and "...[manages] data used in conducting clinical studies..." which Examiner interprets as reading on designing or setting up and running a clinical study or clinical trial (Colon; column 1, lines 60-63, Abstract).

Furthermore, the Examiner respectfully submits that Colon teaches a study management center storing clinical study data in a database in which the data is input into standardized forms

(reads on protocols or templates), that the data are stored in the database tables which is additionally utilized for statistical analysis and automatic assignment of participants in clinical studies and trials and which "is controlled according to scientifically developed mathematical and statistical methods" and "consistent operation...across all activities" (reads on the standardization of a prior clinical trial being stored in a database) (Colon; Abstract, column 1, lines 47 to column 2, line 26, column 3, lines 14-22, column 4, lines 3-26, column 7, line 66 to column 8, line 1). Additionally, Examiner notes that the DeBusk reference teaches "software module objects ...[that]...are user created objects which represent individual templates..." that "allow for the development of custom software modules representative of the procedure for which information is to be managed" and "a standardization node to generate models of individual cases, previously created, for use in analyzing utilization"(reads on stored in a database in the form of a software template based on old clinical trials) (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-53, column 12, line 21 to column 13, line 34, column 14, line3 to column 15, line 30).

In addition, Examiner notes that in both the Colon and DeBusk references any new study includes the design of the study and furthermore that there is no component in the claim language of system claims 1, 19, or 43 that actually performs the designing, but rather a processor running a program that designs and tracks.

Thus, Examiner respectfully reasserts that the system of Colon, DeBusk, Edelson, and Umen teaches the limitations that are argued by Appellant in Section (A),

(B) Claim 1: DeBusk does not teach the standardization of a prior clinical trial being stored in a database in the form of a software template (Issue 1).

In response to Appellant's argument that DeBusk fails to teach the standardization of a prior clinical trial being stored in a database in the form of a software template, the Examiner respectfully submits that the combination of the applied references teaches this limitation as detailed in the prior Office Action (Paper Number 13). In particular, Examiner notes that Colon teaches a study management center storing clinical study data in a database in which the data is input into standardized forms (reads on protocols or templates), that the data are stored in the database tables which is additionally utilized for statistical analysis and automatic assignment of participants in clinical studies and trials and which "is controlled according to scientifically developed mathematical and statistical methods" and "consistent operation...across all activities" (reads on the standardization of a prior clinical trial being stored in a database) (Colon; Abstract, column 1, lines 47 to column 2, line 26, column 3, lines 14-22, column 4, lines 3-26, column 7, line 66 to column 8, line 1). Furthermore, Examiner notes that the DeBusk reference teaches "software module objects ...[that]...are user created objects which represent individual templates..." that "allow for the development of custom software modules representative of the procedure for which information is to be managed" (reads on stored in a database in the form of a software template) (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-53, column 12, line 21 to column 13, line 34, column 14, line3 to column 15, line 30). Examiner also notes that in column 8, lines 41-53, DeBusk teaches the argued limitation by reciting:

> "In a further preferred embodiment of the present invention, the information generated by the case node functionality may be used by a standardization node to generate models of

individual cases, previously created, for use in analyzing utilization. Each case to be studied would be converted into a model module by this node and collectively the desired cases would be collected into a study module. This study module would then be subject to the functionality of the standardization node to be analyzed for standardization opportunities, cost comparison studies or a variety of other comparisons designed to allow the user to better track and optimize resource utilization."

With respect to Appellant's argument (page 6, lines 16-20 of Appellant's Brief) that the DeBusk reference "stores modular reusable standard software modules that are selectable to represent a future clinical procedure to be conducted," Examiner notes that the DeBusk reference teaches "the user may create the various container, resource and data objects that will be used to create the module representing a given clinical pathway. Alternatively, the user may select such objects from pre-configured libraries of such objects or by copying such objects from clinical pathways already created" (emphasis added). Thus DeBusk teaches both the creation of and the selecting of modules or templates. Furthermore, it is respectfully noted that that it was not the DeBusk reference alone that was used to reject claim 1 under 35 U.S.C. § 102, but rather the combination of Colon and DeBusk used for the rejection under 35 U.S.C. § 103.

With respect to Appellant's argument (page 7, line 3 of Appellant's Brief) that "[r]andomization of participants is not the design of the study", Examiner notes that in both the Colon and DeBusk references any new study includes the design of the study and furthermore that there is no component in the claim language of system claims 1, 19, or 43 that actually performs the designing, but rather a processor running a program that designs and tracks.

Thus, Examiner respectfully reasserts that the system of Colon and DeBusk, teaches the limitations of claim 1 that are argued by Appellant in Section (B).

(C) Claims 6 and 7: Colon does not teach a main processor and main database in an organizational environment that includes other databases with information for formulating clinical trials (Issue 1).

In response to Appellant's argument that Colon fails to teach a main processor and main database in an organizational environment that includes other databases with specialized information useful in formulating clinical trials, the Examiner respectfully submits that the combination of the applied references teaches this limitation as detailed in the prior Office Action (Paper Number 13). In particular, Examiner notes that Colon teaches "a study management center ...at a particular geographical site...in which study data is maintained in a database in the host computer (11) behind a firewall provided in the Internet server computer" (reads on main processor and main database are in an organizational environment which includes other databases) and which includes "tables ... provided for each clinical study" and in which "[t]ables are joined as needed to produce regional and study-level management summaries and databases for statistical analysis" (reads on other databases with specialized information useful in formulating clinical trials) (Colon; Figure 4, Items 47-53, column 2, line 58 to column 3, line 22, column 5, lines 5-45, column 6, lines 21-52, column 6, lines 60-66, column 7, lines 26-61).

In response to Appellant's argument that Colon's databases "relate[s] to the conduction of an already-designed clinical trial and thus has no need for databases with information for formulating clinical trials," Examiner notes that in both the Colon and DeBusk references any new study includes the design of the study and furthermore that there is no component in the claim language of system claims 6 or 7 that actually performs the formulating, but rather the

storing in databases of "specialized information useful in formulating clinical trials." In addition, Examiner respectfully notes that there is nothing in the claim language of claims 6 or 7 that precludes use of this system or of these databases for an existing clinical trial.

In response to Appellant's accusation in the paragraph bridging pages 7 and 8 of Appellant's Brief that the Examiner "has pulled the two halves of this quote from completely separate portions of Colon, thereby completely misrepresenting the Colon's teachings," Examiner respectfully submits that the source of Examiner's quote is column 2, line 58 to column 3, line 34 of the Colon reference, and not, as asserted by Appellant, column 2, lines 59-61 and the Abstract. Furthermore, it is noted that column 2, lines 59-61 and the Abstract, were never cited together by the Examiner in the Final Office Action, as presently asserted by Appellant.

In response to Appellant's argument on page 8, lines 10-12 of Appellant's Brief that Colon's databases included "data for conducting a clinical trial rather than formulating one," this argument has already been addressed in that the disputed claims never recite a component that actively formulates a clinical trial.

(D) Claim 43 does not differ from claim 19 in the manner suggested by the Examiner (Issue I).

In the first Office Action (Paper Number 9), Examiner included a statement in the paragraph bridging pages 7 and 8 explaining Examiner's interpretation of the differences between the independent claims. In response to Appellant's taking exception to this statement, Examiner agrees to withdraw this statement. However, it is respectfully submitted that claim 43 recites features already rejected in the rejection of claim 19, and thus does not disclose a

patentable distinction over the applied art of record for the same reasons given for claim 19, and incorporated herein.

(E) Claims 43 and 44: neither Colon nor DeBusk suggest the input of information with regard to completion of tasks and tracking the completion at a user processor (Issue 1).

In response to Appellant's argument on page 9, lines 1-17 of Appellant's Brief that the applied references fail to teach the input of information with regard to completion of tasks and tracking the completion of tasks in the protocol at a user processor, the Examiner respectfully submits that the combination of the applied references teaches this limitation as detailed in the prior Office Action (Paper Number 13). In particular, Examiner notes that Debusk teaches "tracking resource utilization in individual patient cases ...[and] software allows the user to create case modules by selecting an already configured procedural pathway and adding patient and doctor specific information to it ... the user may then easily input information concerning the usage of the resources populating the clinical pathway and maintain a history of resource usage, costing information and/or clinical outcome ... provides for a historical database of resource utilization" (reads on the input of information with regard to completion of tasks and tracking the completion of tasks in the protocol at a user processor) (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56).

Furthermore, DeBusk teaches:

"...a health-care information management system that utilizes modular and reusable software objects to allow for user configuration. The disclosed information management

system allows for the creation by the user software objects representative of specific events and resources which will occur or be utilized during the provision of health-care to patients. These user configured software modules then allow the user to track the provision of health-care, the utilization of resources during the provision of health-care, the allocation of resources to perform medical procedures and identify opportunities for enhancing efficiencies in the provision of health-care services. In on embodiment of the invention described, the system allows for the user to create, manage and maintain software modules representing specific clinical pathways to be performed in a health-care institution. The user creates these modules using user configurable software objects that function to represent containers, resources and data. The software objects are modular and re-usable and allow the user to select components for creation of the modules. The created modules may then be used to provide information management relating to the provision of the medical procedures represented by the clinical pathway modules" (DeBusk; Abstract) (emphasis added).

Examiner interprets this to read on input of information with regard to completion of tasks and tracking the completion at a user processor. In particular the above passage makes clear that the user creates clinical pathway modules that represent containers, resources, and data relating to the provision of medical procedures. It is not clear how this teaching is narrowly construed by Appellant to be merely "resource utilization."

(F) Claims 2 and 19: Colon and DeBusk also do not suggest a program that permits the design of a clinical trial in the form of a protocol of tasks to be completed and does not track the completion of the tasks in the protocol at a user processor (Issue 2).

In response to Appellant's argument the Examiner respectfully submits that Colon teaches a study management center storing clinical study data in a database in which the data is input

into standardized forms (reads on protocols or templates), that the data are stored in the database tables which is additionally utilized for statistical analysis and automatic assignment of participants in clinical studies and trials and which "is controlled according to scientifically developed mathematical and statistical methods" and "consistent operation...across all activities" (reads on the standardization of a prior clinical trial being stored in the form of a protocol) (Colon; Abstract, column 1, lines 47 to column 2, line 26, column 3, lines 14-22, column 4, lines 3-26, column 7, line 66 to column 8, line 1). Additionally, Examiner notes that the DeBusk reference teaches "software module objects ...[that]...are user created objects which represent individual templates..." that "allow for the development of custom software modules representative of the procedure for which information is to be managed" and "a standardization node to generate models of individual cases, previously created, for use in analyzing utilization" (reads on stored in a database in the form of a protocol of tasks) (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-53, column 12, line 21 to column 13, line 34, column 14, line3 to column 15, line 30).

Examiner also notes that in column 8, lines 41-53, DeBusk teaches the argued limitation by reciting:

> "In a further preferred embodiment of the present invention, the information generated by the case node functionality may be used by a standardization node to generate models of individual cases, previously created, for use in analyzing utilization. Each case to be studied would be converted into a model module by this node and collectively the desired cases would be collected into a study module. This study module would then be subject to the functionality of the standardization node to be analyzed for standardization opportunities, cost comparison studies or a variety of other comparisons designed to allow the user to better track and optimize resource utilization."

Furthermore, DeBusk teaches:

> "...a health-care information management system that utilizes modular and reusable software objects to allow for user configuration. The disclosed information management system allows for the creation by the user software objects representative of specific events and resources which will occur or be utilized during the provision of health-care to patients. These user configured software modules then allow the user to track the provision of health-care, the utilization of resources during the provision of health-care, the allocation of resources to perform medical procedures and identify opportunities for enhancing efficiencies in the provision of health-care services. In on embodiment of the invention described, the system allows for the user to create, manage and maintain software modules representing specific clinical pathways to be performed in a health-care institution. The user creates these modules using user configurable software objects that function to represent containers, resources and data. The software objects are modular and re-usable and allow the user to select components for creation of the modules. The created modules may then be used to provide information management relating to the provision of the medical procedures represented by the clinical pathway modules" (DeBusk; Abstract) (emphasis added).

Examiner interprets this to read on input of information with regard to completion of tasks and tracking the completion at a user processor, in that user-created modules provide information management relating to the provision of the medical procedures represented by the clinical pathway modules.

Finally, Examiner notes that in both the Colon and DeBusk references any new study includes the design of the study and furthermore that there is no component in the claim language of system claims 2 or 19 that actually performs the designing, but rather a processor running a program that designs and tracks.

(G) Claims 5 and 22: Edelson does not suggest a main processor and a subsidiary processor periodically operating to synchronize replicated and changed data at the main database and the subsidiary database with changes at said main database predominating over changes at said subsidiary database (Issue 2).

In response to Appellant's argument on page 10 of Appellant's Brief that the applied references fail to teach a main processor and a subsidiary processor periodically operating to synchronize the replicated and changed data at the main database and the subsidiary database, the Examiner respectfully submits that replication is the process of making a replica or copy of something and synchronization ensures that the copy is current or updated, and that the combination of the applied references teaches this limitation as detailed in the prior Office Action (Paper Number 13). In particular, Examiner notes that Edelson teaches data that is "preferably either synchronized or refreshed at intervals (e.g. overnight) from source databases" as well as teaching that "[e]ach data warehouse 212 maintains replicated copies of relevant data sets obtained by read-only access of remote databases 210, which data sets are maintained synchronously with updated source data at remote databases 210, or are periodically refreshed therefrom, preferably at frequent intervals" (emphasis added) (Edelson; column 7, lines 15-32, column 8, lines 4-10, column 46, lines 47-51, column 47, lines 8-20, column 48, lines 4-46).

With regard to Appellant's mention of Examiner's quoted passages, Examiner notes that Appellant appears to rely upon only a small subset of Examiner's cited references. Further it is the entire applied reference(s), and not only the cited passages that must be considered when evaluating whether or not the applied references teach the cited limitations.

With regards to Appellant's argument that "the data at the remote source is read-only and thus can not be replicated there," Examiner notes that this information is taken out of context, as the remote data is only maintained as read-only for remote access at times that the synchronization is not taking place (Edelson; column 48, lines 4-46).

(H) Claims 15, 16, 32, and 33: Applied references do not suggest a site management module for indicating conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location (Issue 2).

In response to Appellant's argument on page 10 of Appellant's Brief that the applied references fail to teach a site management module for indicating the conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location, the Examiner respectfully submits that the combination of the applied references teaches these limitations as detailed in the prior Office Action (paper number 13).

In particular, Colon teaches "a computer system (11, 12, 13) and method for managing data used in conducting clinical studies concerning subjects at a plurality of participating, geographically distributed clinical sites, each participating clinical site having a computer (17, 18, 19) for inputting, transmitting and receiving data over the Internet (15). An Internet network server computer (13) is interfaced to a database host computer (11) through a private network" (Colon; Abstract) and "[t]he system captures data in its database through appropriate input forms developed for the specific clinical study. Data is stored online and reports are produced in real time to study investigators and to the sponsor regarding sites that are participating, recruitment levels by participating site, patient follow-up, and significant events. The database will also

provide the sponsor with an online accounting of study funds distribution" (Colon; column 1, line 64 to column 2, line 4), and "[r]eferring to FIG. 4, tables 47-53 are provided for each clinical study. The site table 47 contains one row 25 for each site (Site 1, Site 2 . . . Site n) in a study and contains contact information for the remote clinical sites. The user table 48 contains one row 25 for each authorized participating person or office (user) for accessing information and contains contact information related to the user. The permission table 49 contains one row for each site or region the user is authorized to access. Fields in table 49 contain flags (on/off) that are used to authorize a user for access to information about sites, regions and study level information (Colon; column 5, lines 14-24). Examiner interprets this to read on site management module for indicating the conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location.

Additionally, Edelson teaches "[c]urrent and historical reports can, subject to the access controls described herein, be patient-specific, prescriber-specific or organization-specific and can be aggregated across various groups, pools, geographical regions, conditions, drugs, or time periods or combinations of any of the foregoing to provide a valuable data resource to health care providers, patients, managed care organizations, government agencies and others" (Edelson; column 38, lines 41-48). Examiner interprets this to read on site management module for indicating the conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location.

DeBusk teaches an "information management system is installed on the general purpose computer and operates to collect, store, maintain and manage health-care related information. In the preferred embodiment of the present invention the information management system is

comprised of individual software objects which can communicate with each other in order to facilitate the information management function of the system. The software objects are configurable by the user to represent health-care related procedures in a fashion that allows for the development of custom software modules representative of the procedure for which information is to be managed" (DeBusk; column 1, lines 36-48) and "[t]he management of outside and inside resources requires the consideration of two different sets of problems. Typically, the outside resources will primarily include the supplies which must be ordered from outside vendors, be delivered to the location and be provided at the appropriate time and place for the performance of the procedure. The inside resources will include the labor resources, equipment owned and maintained by the location and facilities at the location such as OR's, radiology, laboratories, etc." Examiner interprets this to read on site management module for indicating the conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location.

(I) Claims 16 and 33: Neither Colon nor DeBusk suggest that information about the completion of tasks in the protocol at a certain geographical location are entered by a subsidiary user processor in a subsidiary database, and a site management module updates a portion of the protocol related thereto (Issue 2).

In response to Appellant's argument on page 11 of Appellant's Brief that the applied references fail to teach this limitation, Colon teaches "a computer system (11, 12, 13) and method for managing data used in conducting clinical studies concerning subjects at a plurality of participating, geographically distributed clinical sites, each participating clinical site having a

computer (17, 18, 19) for inputting, transmitting and receiving data over the Internet (15). An Internet network server computer (13) is interfaced to a database host computer (11) through a private network" (Colon; Abstract) and "[t]he system captures data in its database through appropriate input forms developed for the specific clinical study. Data is stored online and reports are produced in real time to study investigators and to the sponsor regarding sites that are participating, recruitment levels by participating site, patient follow-up, and significant events. The database will also provide the sponsor with an online accounting of study funds distribution" (Colon; column 1, line 64 to column 2, line 4), and "[r]eferring to FIG. 4, tables 47-53 are provided for each clinical study. The site table 47 contains one row 25 for each site (Site 1, Site 2 . . . Site n) in a study and contains contact information for the remote clinical sites. The user table 48 contains one row 25 for each authorized participating person or office (user) for accessing information and contains contact information related to the user. The permission table 49 contains one row for each site or region the user is authorized to access. Fields in table 49 contain flags (on/off) that are used to authorize a user for access to information about sites, regions and study level information (Colon; column 5, lines 14-24). Examiner interprets this, in addition to previously cited art, to read on completion of tasks in the protocol at a certain geographical location are entered by a subsidiary user processor in a subsidiary database and a site management module updates a portion of the protocol related thereto.

Furthermore, Edelson teaches "[w]hen drug specification is completed to the physician's satisfaction, Send Rx button 80 is pressed to output the newly created electronic prescription in any desired form such as to print, to local or remote storage or to remote file transfer as an electronic prescription. The electronic prescription can be transmitted across a network for

fulfillment by any specified pharmacy, for example, the patient's preferred pharmacy or a pharmacy preferred by the patient's drug benefit company for the particular patient's locality." (Edelson; column 26, lines 56-64). Examiner interprets this to read on information about the completion of tasks in the protocol at a certain geographical location are entered by a subsidiary user processor in a subsidiary database, and a site management module updates a portion of the protocol related thereto.

(J) Claims 17 and 34, Edelson does not suggest transferring from a main processor to a portable processor a copy of a portion of a main database related to a site for a clinical trial in a certain geographical area, the main processor locking the portion of the main database that was copied, the portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and the portable processor transferring and updating the main database with the modified copy of the data and unlocking that portion of the main database (Issue 2).

Regarding Appellant's arguments, on page 12 of Appellant's Brief, that Edelson provides "no details regarding locking and unlocking portions of any databases" Examiner notes that Edelson teaches data that is "preferably either synchronized or refreshed at intervals (e.g. overnight) from source databases" as well as teaching that "[e]ach data warehouse 212 maintains replicated copies of relevant data sets obtained by read-only access of remote databases 210, which data sets are maintained synchronously with updated source data at remote databases 210, or are periodically refreshed therefrom, preferably at frequent intervals" (emphasis added) (Edelson; column 7, lines 15-32, column 8, lines 4-10, column 46, lines 47-51, column 47, lines

8-20, column 48, lines 4-46). Examiner interprets this to read on "transferring from a main processor to a portable processor a copy of a portion of a main database related to a site for a clinical trial in a certain geographical area, the main processor locking the portion of the main database that was copied," and "transferring and updating the main database with the modified copy of the data and unlocking that portion of the main database" since providing read-only access is a form of locking a portion of the database, as the remote data is only maintained as read-only for remote access at times that the synchronization or copy procedure is not taking place and is unlocked at the time of the synchronization (Edelson; column 48, lines 4-46).

(K) Claim 44: Edelson does not suggest replicating to a subsidiary database a portion of data relating to clinical trials in a certain geographical location (Issue 2).

In response to Appellant's argument on pages 12-13 of Appellant's Brief that Edelson does not suggest replicating to a subsidiary database a portion of data relating to clinical trials in a certain geographical location, the Examiner respectfully submits that replication is the process of making a replica or copy of something and synchronization ensures that the copy is current or updated, and that the combination of the applied references teaches this limitation as detailed in the prior Office Action (Paper Number 13). In particular, Examiner notes that Edelson teaches data that is "preferably either synchronized or refreshed at intervals (e.g. overnight) from source databases" as well as teaching that "[e]ach data warehouse 212 maintains replicated copies of relevant data sets obtained by read-only access of remote databases 210, which data sets are maintained synchronously with updated source data at remote databases 210, or are periodically refreshed therefrom, preferably at frequent intervals" (emphasis added) (Edelson; column 7, lines

15-32, column 8, lines 4-10, column 46, lines 47-51, column 47, lines 8-20, column 48, lines 4-46).

With regard to Appellant's mention of Examiner's quoted passages, Examiner notes that Appellant apparently relies upon a small subset of Examiner's cited references. Further it is the entire applied reference(s), and not only the cited passages that must be considered when evaluating whether or not the applied references teach the cited limitations.

With regards to Appellant's argument on page 13, lines 8-9 of Appellant's Brief that "the data is not replicated to the remote database because the remote database is read-only," Examiner notes that this information is taken out of context, as the remote data is only maintained as read-only for remote access at times that the synchronization is not taking place (Edelson; column 48, lines 4-46).

(L) Claims 25-27 and 29-31: Umen does not suggest displaying at a user processor and subsidiary user processor which are operative to display a clinical trial protocol, a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task (Issue 3).

In response to Appellant's argument on pages 13-14 of Appellant's Brief that Umen does not suggest these limitations, Umen teaches "the Status Report option 56c. Upon selection of the status report option, the DMUI scans the detail files of the selected study entry and then displays a tabular list 66 of protocol and results details that have not, as yet, been entered into the detail files of the selected study entry. The status report procedure allows the user to quickly ascertain whether any necessary information is required to complete a study entry." In addition, Umen

discloses General Protocol Information Report and Detail Entry Reports. (Umen; Figure 3, Item 56c, Figure 5, Figure 6, Figure 7,column 10, lines 22-30). Examiner interprets this to read on these limitations.

Furthermore, in response to Appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed Cir. 1986). In addition, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this regard, Examiner notes that Colon teaches a list of patient visits (Colon; Figure 4, column 6, lines 1-4), and Edelson teaches "[d]rug lists or individual drug selections or suggestions may be presented to prescriber-users in any of a variety of ways...," (Edelson; Figure 8 (which shows minor tasks that make up a major task indented under the major task), column 5, lines 20-28). Examiner respectfully submits that the proper combination of these references clearly reads on these limitations.

(M) Claims 10 and 45: None of the applied references suggests the program automatically indicating the completion of a common major task in separate protocols when all of the minor related tasks are completed (Issues 3 and 4).

With regard to Appellant's argument concerning this limitation, Edelson teaches "system also provides, for example in the patient's history record, notification from a pharmacy, or from a

drug benefit plan linked to the pharmacy, of fulfillment of a prescription" (reads on automatically indicating the completion of a major task when all of its minor related tasks are completed), (Edelson; column 7, lines 15-32, column 8, lines 4-10, column 27, lines 44-54, column 46, lines 47-51, column 47, lines 8-20, column 48, lines 4-46). Examiner interprets the notification of the fulfillment of the prescription as the completion of a minor task, with the major task being the updating of the patient history record. As such, it is respectfully submitted that the cited portions have clear relevance to the cited feature.

(N) Prior Art Rejections (Issues 1-4).

In response to Appellant's arguments, all of the limitations which Appellant disputes are missing in the applied references have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the combined teachings of Colon, DeBusk, Edelson, and Umen, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the 35 USC § 103 rejections given in the preceding sections of the present document and in the prior Office Action (paper number 13), and incorporated herein. In particular, Examiner notes that a main database of information concerning prior clinical trials and resources available to conduct future clinical trials the information concerning prior clinical trials being at least in part in the form of a protocol, the protocol of a prior clinical trial being stored in said main database, and the protocol of a prior clinical trial being stored in said main database in the form of a software template are taught by the cited references. In particular, please note (Colon; see at least Abstract, Figure 1, Item 12, column 1, line 35 to column 2, line 4, column 2, line 58 to column 3, line 22, column 3, lines 15-23, column 6, lines 1-14, lines 50-51, column 6, line 58 to column 7, line 31, column 7, lines 45-54), (DeBusk; column 6, lines 33-49,

column 7, lines 40-59, column 8, lines 5-53, column 12, line 21 to column 13, line 34, column 14, line3 to column 15, line 30) as specifically applied in the rejections given above and incorporated herein. Furthermore, with respect to Appellant's argument that the applied references do not suggest the design of a clinical trial, Examiner respectfully notes that there is nothing in the claim language of claims 1, 19, or 43 that precludes use of this system for an existing clinical trial. Additionally, Colon's "invention allows larger studies to be conducted..." and "...[manages] data used in conducting clinical studies..." which Examiner interprets as reading on designing or setting up and running a clinical study or clinical trial (Colon; column 1, lines 60-63, Abstract).

Furthermore, the Examiner respectfully submits that Colon teaches a study management center storing clinical study data in a database in which the data is input into standardized forms (reads on protocols or templates), that the data are stored in the database tables which is additionally utilized for statistical analysis and automatic assignment of participants in clinical studies and trials and which "is controlled according to scientifically developed mathematical and statistical methods" and "consistent operation...across all activities" (reads on the standardization of a prior clinical trial being stored in a database) (Colon; Abstract, column 1, lines 47 to column 2, line 26, column 3, lines 14-22, column 4, lines 3-26, column 7, line 66 to column 8, line 1). Additionally, Examiner notes that the DeBusk reference teaches "software module objects ...[that]...are user created objects which represent individual templates..." that "allow for the development of custom software modules representative of the procedure for which information is to be managed" and "a standardization node to generate models of individual cases, previously created, for use in analyzing utilization"(reads on stored in a

database in the form of a software template based on old clinical trials) (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-53, column 12, line 21 to column 13, line 34, column 14, line3 to column 15, line 30).

In addition, Examiner notes that in both the Colon and DeBusk references any new study includes the design of the study and furthermore that there is no component in the claim language of system claims 1, 19, or 43 that actually performs the designing, but rather a processor running a program that designs and tracks.

Thus, Examiner respectfully reasserts that the system of Colon, DeBusk, Edelson, and Umen teaches each and every claimed limitation. In addition, each point of argument provided by Appellant in the Appeal Brief filed 3/29/04 has been carefully considered and addressed in the instant Examiners Answer, as the Examiner considers the Appeal Brief to be a detailed response to the Examiner's grounds of rejection.

(O) Claims 35 and 36 are sufficiently definite (Issue 5).

In the final Office Action (Paper Number 13), Examiner had maintained the rejection of claims 35-38 under 35 U.S.C. § 112, second paragraph. In view of Appellant's Arguments (Section VIII of the Appellant's Brief), Examiner agrees to hereby withdraw this rejection.

Conclusion

Appellant's arguments at pages 5-16 of the Appeal Brief do not appear to persuasively require a withdrawal of the Examiner's grounds of rejection. As specified in the remarks and rebuttals given above, Appellant's arguments apparently fail to appreciate the clear and

unmistakable suggestions provided in the prior art of record, and relied upon by the Examiner for motivation to combine well-known elements of the prior art. As such, it is respectfully submitted that an explanation based on logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention that support a holding of obviousness has been adequately provided by the motivations and reasons indicated by the Examiner both in the present Examiner's Answer as well as the previous Office Action (paper number 13), *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter., 4/22/93).

Thus, in light of the reasons and responses given above, it is respectfully submitted that a *prima facie* case of obviousness has been clearly established by the Examiner.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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June 21, 2004

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